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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/727,911

12/04/2003

Maxime Lampilas

FRAV2002/0034US NP

7536

5487

7590

05/25/2006

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,911

Applicant(s)

LAMPILAS ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) 24-39 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-23, 40 and 41 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-41 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group V in the reply filed on March 27, 2006 is acknowledged. The traversal is on the ground(s) that examining all of the pending claims presents no undue burden on the Examiner. This is not found persuasive because the compounds, compositions, method of use and process of preparing the compounds of formula I where X is $-C(O)-NR_8-$ and n is 1 is patentably distinct from the compounds, compositions, method of use and process of preparing the compounds of formula I where X is a $-C(O)-O-$ and n is 1, which is patentably distinct from the compounds, compositions, method of use and process of preparing the compounds of formula I where X is $-C(O)-NR_8-CH_2-$ and n is 1, etc.

A heterocyclic moiety having a bridged and fused diazepine ring system is a structurally dissimilar compound which is classified in various subclasses under classes 540, 544 and 546 and the corresponding classification in 514 for the method claims with respect to the number and position of any additional hetero atoms and for the size of the ring. The compounds of formula I where X is $-C(O)-NR_8$ is classified in class 546 and the corresponding classification in 514 for the method claims.

(1) Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.

Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where X and n form the ring system 2,5-methano-1H-2,4-benzodiazepin-3-one be patentably distinct from a whole compound where a X and n form 2,6-methano-3,4,6-benzoxadiazocin-5-one? If a reference for one would not be a reference for the other, then restriction is considered proper. Community of properties is not enough to keep a 2,5-methano-1H-2,4-benzodiazepin-3-one and 2,6-methano-3,4,6-benzoxadiazocin-5-one in the same Markush claim, where the Markush expression is applied only to a portion of a chemical compound. It is the compound as a whole a 2,5-methano-1H-2,4-benzodiazepin-3-one vs. 2,6-methano-3,4,6-benzoxadiazocin-5-one, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

(2) The degree of burden on the examiner is high. The class/subclass search on the elected invention where the compounds of formula I are a 2,5-methano-2,4-diazepin-3-one cores would be as follows: class 514, subclass 292 and 293 and class 546, subclasses 82, 83 and 84 which involved 1482 US patents. The classes and

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subclass mentioned above represent only the degree of burden within the U.S. Patent Classification System this does not include the search required in the prior art of journal articles and foreign patents.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 24-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 14, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-23, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-9, 11-23, 40 and 41 are vague and indefinite in that it is not known what is meant by general formula. A formula is not general when all of the variables are defined. Deletion of "general" is suggested.
- b) Claims 1-9, 11-23, 40 and 41 are vague and indefinite in that it is not known what is meant by the nucleus of the aryl in the definition of R.

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- c) Claims 1-7, 9, 11-23, 40 and 41 are vague and indefinite in that it is not known what is meant by the moiety $\text{O-CH}_2\text{-CH}_2\text{-S(O)}_m\text{-R}$, where the repeater of the O atom in the S(O)_m is not a subscript in the definition of R_8 .
- d) Claim 9 recites the limitation " $\text{-O-(CH}_2\text{)}_2\text{---O-CH}_3$ and $\text{-O-CH}_2\text{-(2,2-dimethyl-1,3-dioxolan-4-yl)}$ " in the definition of R' . There is insufficient antecedent basis for this limitation in the claim.
- e) Claim 10 is vague and indefinite in that it is not known what is meant by 4_{H} in the nomenclature of the second species on page 125.
- f) Claim 10 is vague and indefinite in that it is not known what is meant by 1_{H} in the nomenclature of the third species on page 125.
- g) Claim 10 is vague and indefinite in that it is not known what is meant by 4,7-methanopyrazolo[3,4-e]diazepine in the nomenclature of the eighth species on page 125, which is missing the positioning of the nitrogen atoms in the diazepine.
- h) Claim 10 is vague and indefinite in that it is not known what is meant by the 2(aminocarbonyl) in the nomenclature of the tenth species on page 125.
- i) Claim 10 recites the limitation "methoxyethoxy" in the nomenclature of the twelfth species on page 125. There is insufficient antecedent basis for this limitation in the claim.
- j) Claim 10 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species on page 126 which is missing an open parenthesis.

- k) Claims 11-17 are vague and indefinite in that it is not known what is meant by the definition of R'' , which is stated as being defined above, however, this is not so.
- l) Claim 16 is vague and indefinite in that it is not known what is meant by the definition of n , which is as defined in claim 11, however, n is not defined in claim 11. See formula IV.
- m) Claim 16 is vague and indefinite in that it is not known what is meant by the definition of A and n , which is as defined in claim 11, however, A and n are not defined in claim 11. See formula V.
- n) Claim 16 is vague and indefinite in that it is not known what is meant by the definition of A and n , which is as defined in claim 11, however, A and n are not defined in claim 11. See formula VI.
- o) Claim 16 is vague and indefinite in that it is not known what is meant by the variable R_{11} , which is not defined within the claim.
- p) Claim 16 is vague and indefinite in that it is not known what is meant by the definition of R_{11} , where there is no variable R_{11} in the claim.
- q) Claim 16 is vague and indefinite in that it is not known what is meant by the variable R_3 , which is not defined within the claim.
- r) Claim 16 is vague and indefinite in that it is not known what is meant by the definition of A , R_3 and n'' , which is as defined in claim 11, however, A , R_3 and n'' are not defined in claim 11. See formulae VIII and VIII'.

- s) Claim 17 is vague and indefinite in that it is not known what is meant by the definition of A and n, which is as defined in claim 11, however, A and n are not defined in claim 11. See formula VII.
- t) Claim 17 is vague and indefinite in that it is not known what is meant by the variable R₃, which is not defined within the claim.
- u) Claim 17 is vague and indefinite in that it is not known what is meant by the definition of A, R₃ and n", which is as defined in claim 11, however, A, R₃ and n" are not defined in claim 11. See formula VIII.
- v) Claims 22, 23, 40 and 41 are vague and indefinite in that it is not known what is meant by the additional active component, i.e. β -lactam(ase) medicament, which does not set forth the metes and bounds of the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-10, 20 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 20 of copending Application No. 10/480,019. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula I of the instant invention are embraced by the compounds, compositions and method of use of the compounds of formula I of 10/480,019 where X is $-\text{C}(\text{O})-\text{NR}_n-$ and n is 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

5. Claim 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be stated in the alternative.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman
Primary Examiner Art Unit 1624
May 23, 2006